

Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 3/3/2021 8:16:59 PM
To: Bauer, Jeff [Bauer.Jeff@epa.gov]; Master, Barbora [Master.Barbora@epa.gov]
Subject: FW: P-16-05X3

Importance: High

From: Berger, Tom C.
Sent: Thursday, February 25, 2021 2:19 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Master, Barbora <Master.Barbora@epa.gov>; Price, Amanda <price@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>
Subject: RE: P-16-05X3
Importance: High

Jeff – thanks.

Your latest email states that the work inhalation APF will be 1,000. However, as you previously indicated, EPA has proposed a limit of 1 percent respirable particles in P-16-05X3 to mitigate inhalation exposure to workers when used in customer spray foam (SPF) applications.

Indeed, consistent with the revised engineering report, using the default PNOR mass concentration (C_{total}) of 15 mg/m³ total particles containing the PMN substance, the submitter-specified mass fraction (F_{NCS}) of 0.35 in SPF, the EPA-selected POD of 0.22 mg/m³, and proposed limit of 1 percent respirable particles, **we independently calculate a Fold Factor of only 7.1** for the respirable particle content of P-16-05X3:

1. $PDR = (C_{total})(F_{NCS})(IR)(ED) = (15 \text{ mg/m}^3)(0.35)(0.01)(1.25 \text{ mg/m}^3)(8 \text{ hr/day-shift}) = (0.0525 \text{ mg/m}^3)(1.25 \text{ mg/m}^3)(8 \text{ hr/day-shift}) = 0.525 \text{ mg/day-shift} = 0.0525 \text{ mg/m}^3$
2. $MOE_{NCS} = POD / PDR = (0.22 \text{ mg/m}^3) / (0.0525 \text{ mg/m}^3) = 4.2$
3. $\text{Fold Factor} = MOE_{benchmark} / MOE_{NCS} = 30 / 4.2 = 7.1$

Mandating a specific limit of respirable particles may place an unreasonable burden on customers. The submitter accordingly requests that EPA confirm that, because the proposed 1-percent respirable particle limit, when compared to the analytically determined, worst-case 0.15 percent respirable particle level in P-16-05X3 when used in SPF applications, provides a sufficient margin of safety for workers who may be exposed to the PMN substance during customer use, customers do not need to routinely test particle size distribution for each specific SPF application, e.g., use of different equipment or use at different application parameters.

Otherwise, in lieu of a potentially unworkable mandatory particle size limit, the submitter proposes that EPA instead require use of an industry standard APF 50 respirator to mitigate exposure to workers who may be exposed to P-16-05X3 during customer use. Specifically, factoring in an upper limit of 7 percent respirable particles, and otherwise employing the same assumptions as above, we calculate a Fold Factor of 50 for the respirable particle content of P-16-05X3:

1. $PDR = (C_{total})(F_{NCS})(IR)(ED) = (15 \text{ mg/m}^3)(0.35)(0.07)(1.25 \text{ mg/m}^3)(8 \text{ hr/day-shift}) = (0.3675 \text{ mg/m}^3)(1.25 \text{ mg/m}^3)(8 \text{ hr/day-shift}) = 3.675 \text{ mg/day-shift} = 0.3675 \text{ mg/m}^3$
2. $MOE_{NCS} = POD / PDR = (0.22 \text{ mg/m}^3) / (0.3675 \text{ mg/m}^3) = 0.60$
3. $\text{Fold Factor} = MOE_{benchmark} / MOE_{NCS} = 30 / 0.60 = 50$

Accordingly, P-16-05X3 could contain up to 7 percent respirable particles and still qualify for use of an APF 50 respirator. That is, mandatory use of an APF 50 respirator would equate to an upper limit for respirable particles which is more than a full order of magnitude greater (47x) than the reported level of respirable particles in P-16-05X3 and almost a full order of magnitude greater (7x) than the EPA-proposed 1-percent limit for such particles. This clearly would provide a readily attainable and maintainable margin of safety for workers who may be exposed to P-16-05X3 by inhalation routes during customer use.

Please let us know at that time(s) you are available on Wednesday. We look forward to our call.

Thanks again and best regards,
Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, February 24, 2021 5:32 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Master, Barbora <Master.Barbora@epa.gov>; Price, Amanda <price@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>
Subject: RE: P-16-05X3

Tom,

I sent Sam the engineering and exposure reports January 27, 2021. The fugitive air release looks like it will present a gen pop risk. The work inhalation APF will be 1,000. If you have had the chance to look those exposure over and want to talk about them we can address them as I am still waiting on the final Human Health report.

I will send another email to RAB as to the status of getting the final report and will set up meeting with you on Wednesday next week.

Thanks
Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, February 24, 2021 3:12 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>
Subject: RE: P-16-05X3

Hi Jeff –

The commercial needs here are getting urgent. What is your availability for a conference call on this in the next 5-6 working days?

Thanks – Tom

From: Berger, Tom C.
Sent: Wednesday, February 24, 2021 11:27 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

We have a call on this with the submitter today at 2:00 – any update?

Thanks – Tom

From: Berger, Tom C.
Sent: Friday, February 19, 2021 11:12 AM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

Just checking in on this - thanks

From: Berger, Tom C.
Sent: Wednesday, January 13, 2021 5:25 PM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: P-16-05X3

Hi Jeff –

The submitter asked me to reach out to you regarding timing. Recall that we need to both amend the SNUR (recall that the number of use sites make a SNUN approach unworkable) and the section 5(e) order, neither of which have statutory or regulatory timeframes or deadlines. Can you estimate a timeframe in terms of what you and RAD need to accomplish as well as how long it might be expected to take thereafter to amend the SNUR and the 5(e) order?

Thanks again and best regards,
Tom

Thomas C. Berger
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From: Berger, Tom C.
Sent: Friday, January 8, 2021 1:54 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: FW: P-16-05X3

Hi Jeff –

I hope you had a great holiday!

Just checking in on this.

Thanks again - Tom

From: Master, Barbora <Master.Barbora@epa.gov>
Sent: Thursday, December 31, 2020 11:24 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>
Subject: RE: P-16-05X3

Hi Tom –

I don't have anything new to share with you. Jeff will be back next week (on Tuesday).

Thanks, Barbora

Barbora Master
Team Leader, Risk Management Branch 1
New Chemicals Division
U.S. Environmental Protection Agency
202-343-9899

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, December 29, 2020 5:58 PM
To: Master, Barbora <Master.Barbora@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>
Subject: RE: P-16-05X3

Hi Barbora –

As some time has passed I thought I would check in on this.

Thanks much - Tom

From: Master, Barbora <Master.Barbora@epa.gov>
Sent: Thursday, December 10, 2020 4:43 PM
To: Berger, Tom C. <Berger@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Tom –

I just checked in with the risk assessors, but I don't have anything new to tell you. Your case is still one that we're working through. Unfortunately, I can't commit to a specific end date, but I will do what I can on my end. As you can imagine, a number of people are out of the office during the holiday season, so it's a tough time.

Best, Barbora

Barbora Master
Team Leader, Risk Management Branch 1
New Chemicals Division
U.S. Environmental Protection Agency
202-343-9899

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, December 10, 2020 12:16 PM
To: Master, Barbora <Master.Barbora@epa.gov>; Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Barbora – thanks for the update.

My client was wondering whether this important issue could be resolved this year. Please advise and take any steps you can to expedite.

Thanks again - Tom

From: Master, Barbora <Master.Barbora@epa.gov>
Sent: Tuesday, December 8, 2020 1:57 PM
To: Berger, Tom C. <Berger@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Good Afternoon Tom –

Jeff will be out for the rest of the month. I am monitoring his cases while he is out. I have nothing new to report on your case, unfortunately. I will let you know if I get any update.

-Barbora

Barbora Master
Team Leader, Risk Management Branch 1
New Chemicals Division
U.S. Environmental Protection Agency
202-343-9899

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, December 08, 2020 9:57 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Daniels, Rhys G. <daniels@khlaw.com>; Master, Barbora <Master.Barbora@epa.gov>
Subject: RE: P-16-05X3

Hi Jeff —

With the holidays rapidly approaching I am checking in again.

Thanks — Tom

From: Berger, Tom C.
Sent: Wednesday, December 2, 2020 8:56 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Daniels, Rhys G. <daniels@khlaw.com>; Master, Barbora <Master.Barbora@epa.gov>
Subject: RE: P-16-05X3

Hi Jeff —

Just checking in.

Thanks and best regards,
Tom

From: Berger, Tom C.
Sent: Monday, November 23, 2020 3:25 PM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Daniels, Rhys G. <daniels@khlaw.com>; 'Master, Barbora' <Master.Barbora@epa.gov>
Subject: RE: P-16-05X3

Hi Jeff —

I hope that all is well.

I know it's a short week but just following up with you. Last we communicated with you, you were expecting the QA/QC'd Health Report, as well as a sanitized Exposure Report.

Thanks and best regards,
Tom

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From: Berger, Tom C.

Sent: Wednesday, October 28, 2020 10:03 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Daniels, Rhys G. <daniels@khlaw.com>; Master, Barbora <Master.Barbora@epa.gov>

Subject: RE: P-16-05X3

Jeff – thanks much – please do keep us posted. We look forward to receiving the updated report.

Best regards,
Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>

Sent: Tuesday, October 27, 2020 3:07 PM

To: Berger, Tom C. <Berger@khlaw.com>

Cc: Price, Amanda <price@khlaw.com>; Daniels, Rhys G. <daniels@khlaw.com>; Master, Barbora <Master.Barbora@epa.gov>

Subject: RE: P-16-05X3

Tom,

I want to wait till we get the HH report then I can share that with you and we can work out the Risk Management of the PMN. I am taking your comments on the proposed scenarios into account. Getting the HH report may get to the outcome you presented in September.

Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
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From: Berger, Tom C. <Berger@khlaw.com>

Sent: Tuesday, October 27, 2020 2:51 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Daniels, Rhys G. <daniels@khlaw.com>; Master, Barbora <Master.Barbora@epa.gov>

Subject: RE: P-16-05X3

Jeff – thanks so much. Can you tell us where things are headed from a regulatory standpoint?

From: Bauer, Jeff <Bauer.Jeff@epa.gov>

Sent: Tuesday, October 27, 2020 2:36